

FOOD AND DRUG ADMINISTRATION

Center for Drug Evaluation and Research

Arthritis Advisory Committee (AAC) Meeting

FDA White Oak Campus, Building 31, The Great Room (Rm. 1503)

White Oak Conference Center, Silver Spring, Maryland

March 12, 2012

DRAFT Meeting Agenda

The committee will discuss the anti-nerve growth factor (anti-NGF) drug class that is currently under development and the safety issues possibly related to these drugs. These drugs are being developed for the treatment of a variety of chronic painful conditions including osteoarthritis, chronic lower back pain, diabetic peripheral neuropathy, post-herpetic neuralgia, chronic pancreatitis, endometriosis, interstitial cystitis, vertebral fracture, thermal injury, and cancer pain. The committee will be asked to determine whether reports of joint destruction represent a safety signal related to the anti-NGF class of drugs, and whether the risk benefit balance for these drugs favors continued development of the drugs as analgesics.

8:00 a.m.	Call to Order and Introduction of Committee	Lenore Buckley, M.D. Chair, AAC
8:05 a.m.	Conflict of Interest Statement	Philip Bautista, Pharm.D. Designated Federal Officer, AAC
8:10 a.m.	FDA Introductory Remarks	Bob Rappaport, M.D. Director Division of Anesthetic, Analgesic and Addiction Products (DAAAP) Office of Drug Evaluation II (ODEII) Office of New Drugs (OND), CDER, FDA
8:15 a.m.	INDUSTRY PRESENTATIONS	
10:15 a.m.	Clarifying Questions to Industry	
10:30 a.m.	BREAK	
10:45	FDA PRESENTATION	
12:00 p.m.	LUNCH	
1:00 p.m.	FDA PRESENTATION (cont.)	
1:25 p.m.	Clarifying Questions to the FDA	
1:45 p.m.	Open Public Hearing Session	
2:45 p.m.	BREAK	
2:55 p.m.	Charge to the Committee	
3:00 p.m.	Questions to the Committee/Committee Discussion	
5:30 p.m.	ADJOURNMENT	